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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

GABEL, GAILENE

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 08/27/2002 20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/268,437

Applicant(s)

DING ET AL.

Examiner

Gailene R. Gabel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response filed 5/23/02 in Paper No. 19 is acknowledged and has been entered. Claim 1 has been amended. Currently, claims 1-5 and 10 are pending and under examination.

Rejections Withdrawn

Claim Rejections - 35 USC § 112

2. In light of Applicant's argument, the rejection of claims 1-5 and 10 under 35 U.S.C. 112, first paragraph, enablement rejection, is hereby, withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-5 and 10 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, the specification does not provide literal support for the recitation of "analyte binding areas comprise liquid impervious sheets" in claim 10. Applicant points

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to the specification at page 11, line 15, which discloses use of "polystyrene sheet" but fails to provide literal support for such a recitation set forth in claim 10. Furthermore, none of the originally filed claims recited the limitation in question. Recitation of claim limitation lacking support in the specification or originally filed claims constitutes new matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 1-5 and 10 stand rejected under 35 U.S.C. 102(e) as being anticipated by Wohlstadter et al. (US 6,066,448) for reason of record.

Wohlstadter et al. disclose an electrochemical device comprising a cell or a plurality of cells adapted to hold a sample wherein the cell has a surface (support) having a plurality of analyte binding areas (discrete binding domains) each having a different analyte binding substrate. Wohlstadter et al. further disclose the cell including a plurality of working electrodes each adjacent to an analyte binding area separate from another binding area by a distance, i.e. binding domains spatially aligned and in proximity to a plurality of electrodes, and further including reference electrodes, sensing electrodes, and auxiliary electrode (see column 42, lines 36-49, column 9, lines 53-65,

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and column 11, line 56 bridging to column 12, line 31). The analyte binding areas are localized by coating different binding affinities on different binding substrates, i.e. binding reagents, that bind to at least one analyte of interest (see column 19, lines 25-37). The binding substrates are selected so as to have a desired binding specificity which includes proteins, antibodies, antigens, receptors, epitopes, etc. (see column 20, lines 30-67). The substrates each may have a different antigens or different antibodies (see columns 21-22). The analyte binding areas are supported by liquid impervious sheets such as silicon, glass, plastic, and carbon fibrils including ceramics and Teflon (see columns 11-13).

Additionally, Wohlstadter teaches quantitatively detecting enzyme product in column 22, lines 24-39, wherein the substrate is the analyte of interest and the product of the enzymatic reaction upon the substrate is a reporter agent. (detectable agent).

Response to Arguments

5. Applicant's arguments filed 5/23/02 have been fully considered but they are not persuasive.

A) Applicant argues that liquid impervious sheets, such as polystyrene, are fully supported by the depiction of a cross-section of a solid substrate in Figure 12 in which unbroken slanted lines are used, which clearly indicate that the support is solid and is liquid-impervious. According to Applicant, since the structure sets forth a solid support,

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a recitation of a function, i.e. impermeable to liquid, can be incorporated into a claim without introducing new matter.

In response, a solid support as set forth by Applicant's drawing in Figure 12 does not fully encompass a function as being solely liquid impermeable.

B) Applicant argues that Wohlstadter's use of the phrase "spatial alignment" in connection with the binding domains is merely to describe the location of electrodes in relation to their corresponding analyte binding domains but there is no structural requirement for a working electrode, with its corresponding analyte binding area, to be separate from adjacent binding areas by a minimal distance.

In response to Applicant's argument that in defining a spatial alignment, there is no structural requirement for a working electrode, with its corresponding analyte binding area, to be separate from adjacent binding areas by a minimal distance, Wohlstadter, indeed, define structural requirements for a working electrode with its analyte binding area, to be commensurately separate in distance, so as to achieve high surface area to solution volume ratios (see column 51, lines 53-67).

C) Applicant argues that there is no teaching of the use of electrodes to quantitatively detect enzyme reaction product. The close proximity of the electrodes to the binding area merely induces ECL.

In response to Applicant's contention that there is no teaching of the use of electrodes to quantitatively detect enzyme product, Wohlstadter, indeed, teaches

quantitatively detecting enzyme product in column 22, lines 24-39, wherein the substrate is the analyte of interest and the product of the enzymatic reaction upon the substrate is a reporter agent. (detectable agent).

6. No claims are allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gail Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday to Thursday from 7:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays from 7:00 AM to 3:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gail Gabel
Patent Examiner
Group 1641



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/1641